K030154

MAR 3 1 2003

510(k) SUMMARY

SUBMITTER:	Dideco S.p.A. 86, Via Statale 12 Nord 41037 Mirandola (MO) Italy
CONTACT PERSON:	Luigi Vecchi Phone: 011 39 0535 29811 Fax: 011 39 0535 25229
DATE PREPARED:	January 15, 2003
DEVICE TRADE NAME:	IDEAL: System with Integrated Venous Air Removal, Centrifugal Blood Pump, Pump Holder, Adult Membrane Oxygenator, Heat Exchanger and Arterial Filter
COMMON NAMES:	Hollow Fiber Membrane Oxygenator with Integrated Arterial Filter and Heat Exchanger Venous Defoamer Centrifugal Blood Pump
CLASSIFICATION NAMES:	Cardiopulmonary Bypass Oxygenator Cardiopulmonary Bypass Heat Exchanger Cardiopulmonary Bypass Blood Reservoir Cardiopulmonary Bypass Defoamer Cardiopulmonary Bypass Arterial Line Blood Filter Non-Roller Type Cardiopulmonary Bypass Blood Pump
PREDICATE DEVICES:	SYNTHESIS: Adult Membrane Oxygenator With Integrated Arterial Filter and Hardshell Venous/Cardiotomy Reservoir Mimesys treated (Phosphorylcholine coating hereinafter called PC coating) (k022450) Cobe Revolution Centrifugal Blood Pump, (K011835)

DEVICE DESCRIPTION:

The Ideal, System with Integrated Venous Air Removal, Centrifugal Blood Pump, Pump Holder, Adult Membrane Oxygenator, Heat Exchanger and Arterial Filter is an extracorporeal hemodynamic and gas exchange support system for extracorporeal perfusion. The Ideal consists of a high efficiency, microporous, hollow fiber membrane oxygenator integrated with a heat exchanger and an arterial filter (Synthesis Adult Membrane Oxygenator, K022450), connected to an active venous air removal device (defoamer), a centrifugal pump (Cobe Revolution Centrifugal Blood Pump, K011835) and a pump bracket.

INDICATION FOR USE:

The IDEAL, System with Integrated Venous Air Removal, Centrifugal Blood Pump, Pump Bracket, Adult Membrane Oxygenator, Heat Exchanger and Arterial Filter hereinafter called the IDEAL is a sterile, nonpyrogenic device intended to be used in surgical procedures requiring extracorporeal gas

The IDEAL, System with Integrated Venous Air Removal, Centrifugal Blood Pump, Pump Bracket, Adult Membrane Oxygenator, Heat Exchanger and Arterial Filter hereinafter called the IDEAL is a sterile, nonpyrogenic device intended to be used in surgical procedures requiring extracorporeal gas exchange support. The Ideal is intended for use in operations on adult patients. The Ideal must not be used longer than 6 hours. Contact with blood for longer periods is inadvisable. The Ideal is intended for use with Stöckert Centrifugal Pump Console

TECHNOLOGICAL CHARACTERISTICS:

The Ideal is comprised of an adult membrane oxygenator with an integrated heat exchanger and arterial filter identical to the Synthesis predicate device. The coating is identical to the phosphoryline coating used on the Synthesis predicate device. The Ideal design has been completely reviewed with reference to the defoaming system as compared to the Synthesis' predicate device defoaming system.
The air removal system (defoamer) of the Ideal replaces the air removal function of ordinary venous reservoirs by centralizing venous line air and effectively removing it in a way substantially equivalent to the Synthesis hardshell venous/cardiotomy reservoir. The basic function of all integrated defoamer/oxygenators is the same. That is, a combination blood-gas exchange device with a separate active venous air removal section (defoamer).
The Ideal with reference to the integrated centrifugal blood pump is also identical to the Revolution Pump predicate device. The basic function of all centrifugal pumps is the same, that is, moving blood through the cardiopulmonary bypass circuit by centrifugal force.
Therefore the Ideal duplicates the functionality of the separate predicate devices.
The Ideal is ethylene oxide sterilized and has a nonpyrogenic fluid path. It is for single use only.

BIOCOMPATIBILITY TEST RESULTS:

A complete battery of tests were carried out in accordance with the requirements of ISO 10993-1:1995 and the FDA May 1, 1995 Memorandum on the use of the ISO 10993 standard for biocompatibility testing on the raw materials. The Synthesis device was tested for Hemolysis, Cytotoxicity, Irritation, Acute Systemic Toxicity and Mutagenicity. The Revolution device was tested for Hemolysis, Cytotoxicity, Irritation, Acute Systemic Toxicity and Mutagenicity. Biocompatibility testing performed on Synthesis and Revolution predicate devices have been taken as reference for the Ideal system as the raw materials used in the manufacturing process are identical to those used in both predicate devices. Sterility, Pyrogenicity, ETO residuals and package integrity testing were also conducted. The results of this testing met established specifications.

***IN VITRO* TEST RESULTS:**

In vitro testing was carried out in accordance with the requirements of "Guidance for Cardiopulmonary Bypass Oxygenators 510(k) submissions – Final Guidance for Industry and FDA Staff" issued on November 13, 2000 - "Guidance for Blood Extracorporeal Blood Circuit Defoamer 510(k) Submission" Final Guidance for industry and FDA issued on November 29, 2000 – "Guidance for Cardiopulmonary Bypass Arterial Line Blood Filter 510(k) Submission" Final Guidance for industry and FDA issued on November 29, 2000 and when applicable, following the ISO 7199 (1996) standard for "Cardiovascular Implants and Artificial Organs – Extra Corporeal Blood-Gas Exchangers (Oxygenator)" for providing the data necessary to demonstrate both the substantial equivalence with the predicate devices and also complying with safety and effectiveness requirements. The device aged up to 3 years was tested for operating blood volumes, hemolysis/cell deplation, mechanical integrity and air handling characterization of the integrated venous air removal device. The results of this tests met established specifications. For comparative purposes, the same testing, when applicable, has been conducted also on the Synthesis and Revolution predicate.
The result of the study showed that the device is comparable to the predicate devices concerning with all characteristics.

CONCLUSIONS:

The results of *in vitro* studies demonstrate that the Ideal performs in a manner substantially equivalent to the Synthesis with respect to the main function of ordinary venous reservoirs (defoamers) that is separation and evacuation of gaseous emboli form the venous blood. Previous *in-vitro* data showed that the Ideal performs in a manner substantially equivalent to the Synthesis with respect to the expected main performance parameters associated with ordinary oxygenators with integrated heat exchanger and arterial filter that is transfer of oxygen and removal of carbon dioxide, blood temperature control, removal of arterial blood components aggregates larger than 40 µ. Furthermore, the Ideal performs in a manner substantially identical to the centrifugal pump Revolution predicate device with respect to the basic function of an ordinary centrifugal pump that is propulsion of blood through the cardiopulmonary bypass circuit by centrifugal force.
Data collected show that integration of the active venous air removal device (defoamer) and of the centrifugal pump to the oxygenating module is advantageous in terms of lower operating blood volumes during priming procedures. Moreover air handling test results indicate that air bubbles are equally well handled and purged from venous blood by the Ideal integrated venous air removal device with respect to traditional extracorporeal cardiopulmonary bypass reservoirs.
Therefore it can be concluded that Ideal integrated system duplicates the functionality of the separated predicate devices. Biocompatibility and functional performances of phosphorylcholine coated devices, proved for the Synthesis predicate device, have been taken as reference for the Ideal. Additional testing has also demonstrated the effectiveness of production techniques to assure that the oxygenator is sterile and non-pyrogenic.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 3 1 2003

Dideco S.p.A.
c/o Mr. Barry Sall
Parexel International Corp.
195 West Street
Waltham, MA 02451-1163

Re: K030154
IDEAL, System with Integrated Venous Air Removal, Centrifugal Blood Pump, Pump Holder, Adult Membrane Oxygenator, Heat Exchanger and Arterial Filter
Regulation Number: 21 CFR 870.4360
Regulation Name: Nonroller Type CPB Blood Pump
Regulatory Class: Class III (three)
Product Code: KFM
Dated: January 15, 2003
Received: January 16, 2003

Dear Mr. Sall:

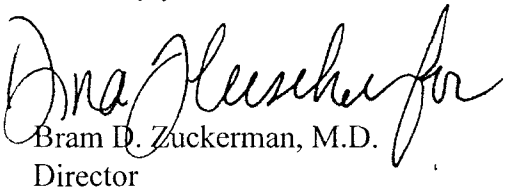
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: IDEAL System with Integrated Venous Air Removal, Centrifugal Blood Pump, Pump Holder, Adult Membrane Oxygenator, Heat Exchanger and Arterial Filter

Indications For Use:

Ideal is intended to be used in surgical procedures requiring extracorporeal gas exchange support. Ideal is intended for use in operations on adult patients. Ideal must not be used longer than 6 hours. Contact with blood for longer periods is inadvisable. Ideal is intended for use with the Stöckert Centrifugal Pump Console.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K030194